Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the efficacy of 14- day concomitant regimen with 14- day high dose esomeprazole and amoxicillin regimen on Helicobacter pylori eradication

Protocol summary

Study aim
Comparison of the efficacy of 14-day concomitant and 14-day high-dose dual therapy on Helicobacter pylori eradication

Design
Phase 3 randomized clinical trial with control group, on 240 patients with Helicobacter pylori infection

Settings and conduct
In this randomized clinical trial, among patients with symptoms of dyspepsia referred to the gastroenterology clinic of Toba in sari city in mazandaran province, upper GI endoscopy was done. 240 patients, accoeding to inclusion & exclusion criteria enrolad the study. randomization are according to random table was extracted from internet

Participants/Inclusion and exclusion criteria
Inclusion criteria was ages between 18 and 80 years who have H. pylori infection and have endoscopic findings of gastric ulcer or erosion, duodenal ulcer or duodenitis and or histologic evidence of intestinal metaplasia. Exclusion criteria: Pregnant or nursing women, those with a history of upper GI surgery, major cardiac, lung, liver or renal diseases, a history of previous H. pylori eradication regimen and history of known side effects to the protocol drugs would be excluded from the study.

Intervention groups
Group receiving high doses of PPI and amoxicillin

Main outcome variables
Success rate of this regimen in eradicating Helicobacter pylori, patient tolerance, drug side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131124015510N4**
Registration date: **2021-06-11, 1400/03/21**
Registration timing: **retrospective**

Last update: **2021-06-11, 1400/03/21**
Update count: **0**

Registration date
2021-06-11, 1400/03/21

Registrant information

Name
Seyed Mohammad Valizadeh Toosi

Name of organization / entity
Mazandaran University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-09, 1399/02/20

Expected recruitment end date
2021-05-10, 1400/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of 14- day concomitant regimen with 14- day high dose esomeprazole and amoxicillin regimen on Helicobacter pylori eradication

Public title
Comparison of quadruple therapy and high dose dual therapy on Helicobacter pylori eradication
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria was ages between 18 and 80 years who have H. pylori positive and have endoscopic findings of gastric ulcer or erosion, duodenal ulcer or duodenitis and or histologic evidence of intestinal metaplasia.
Exclusion criteria:
Pregnant or nursing women, those with a history of upper GI surgery, major cardiac, lung, liver or renal diseases, a history of previous H. pylori eradication regimen and history of known side effects to the protocol drugs would be excluded.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
First, we use a Random Number Generator to extract 240 random numbers from one to 240. These 240 extracted numbers include 1 and 2, which are arranged randomly and then the first number of patients are included in the study Number 1 receives the standard regimen and number 2 receives the study regimen.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients who include the the study would be blind
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
moallem
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2020-04-22, 1399/02/03
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1399.7090

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection
ICD-10 code
B96.81
ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Helicobacter pylori infection
Timepoint
In the beginning of the study when patient enrolled the study
Method of measurement
Evaluation of Helicobacter pylori infection by RUT test or pathology

Secondary outcomes

1

Description
Helicobacter pylori eradication
Timepoint
Six to 8 weeks after end of HP eradication treatment
Method of measurement
H pylori stool antigen test

Intervention groups

1

Description
Control group: Patients receiving the standard 14-day Helicobacter pylori eradication regimen
Category
Treatment - Drugs

2

Description
Intervention group: Patients receiving 14 days high-dose

PPI and amoxicillin regimens for Helicobacter pylori eradication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Toba clinic of Sari city

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

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Khazar bolvard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr sayedi

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Moallem

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Web page address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Valizadeh Toosi

Position

Assistant Professor Mazandaran University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable